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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,292	04/02/1999	DONNA G. ALBERTSON	023070-09140	3543

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/285,292

Applicant(s)

ALBERTSON ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 September 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-14, 16 and 17 is/are allowed.
- 6) ☒ Claim(s) 15 and 18-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 16.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

1. Claims 1-32 are pending.  
  
Claim 4 has been amended.  
  
Claims 33-70 have been cancelled.  
  
Claims 1-32 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Withdrawn Rejections***

***Claim Rejections - 35 USC § 112***

3. The rejection of claims 1-17 under 35 U.S.C. 112, first paragraph, is withdrawn in light of Applicants' arguments.
4. The rejection of claims 1-14, 16-29, 31 and 32 (pages 5 and 6, sections a, b, d and e of Paper number 13) under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of Applicants' arguments.

***Maintained Rejections***

***Claim Rejections - 35 U.S.C. § 112***

5. The rejection of claims 15 and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained.

a. Claims 15 and 30 are vague and indefinite in the recitation "...statistically significant difference." Applicants traverse this rejection and attest that the recitation is expressly defined. This is found unpersuasive.

Applicants recite language allegedly from the specification in support of the phrase, "statistically significant difference". However, Applicants have not pointed out where within the specification this supportive language is found. Applicants should note the page and line numbers of where the language that supports their arguments can be found.

***Claim Rejections - 35 USC § 112***

6. Claims 18-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.


Claims 18, 23, 25 and 26 broadly state a method of estimating the survival expectancy of an animal with cancer, wherein the control sample indicates reduced

survival expectancy. The specification does note that "survival expectancy can refer to a prediction regarding the severity, duration, or progress of a disease..." and "...the length of time an animal is expected to survive...". However, the specification does not provide any objective evidence that supports the estimation of survival expectancy. There is no link evidenced within the specification between high levels of *CYP24* and survival expectancy. While it is art known that persons diagnosed with cancer are at risk of a shorter lifespan, however many patients are known to live to general life expectancies. The specification is merely speculating regarding high levels of *CYP24* with a reduced survival expectancy. One skilled in the art could not be expected to correlate the level of *CYP24* in a biological sample with an estimation of survival expectancy. There should be some valid amount of direction or guidance, as well as presence or absence of working examples presented in the specification that would enable one skilled in the art to perform the method as presented in the recited claims. The predictability of the art in regards to cancer prognosis and the estimation of life expectancies within a population with a disease or disorder is art known to be highly speculative and unpredictable. Therefore, due to the unpredictability of cancer and the absence of any evidence concerning the level of *CYP24* and the estimation of survival expectancy of an animal a person skilled in the art to which it pertains, or with which is most nearly connected would not have a reasonable expectation of success in using the invention and without undue experimentation.

***Conclusion***

7. Claims 1-32 are free of the art.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703) 306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.  
Patent Examiner, Group 1642  
December 13, 2001

  
ALANA M. HARRIS  
Patent Examiner  
Group 1642  
December 13, 2001